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PTO/SB/21 (02-04)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/653,023	
	Filing Date	08/28/2003	
	First Named Inventor	Racchini	
	Art Unit	3736	
	Examiner Name	unknown	
Total Number of Pages in This Submission	7	Attorney Docket Number	LFSS015USCIP

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input type="checkbox"/> Other Enclosure(s) (please identify below):
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<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Response to Missing Parts/Incomplete Application	Remarks	
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Mayumi Maeda Reg. No. 40,075
Signature	
Date	12/14/04

CERTIFICATE OF TRANSMISSION/MAILING	
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.	
Typed or printed name	Jane Silarajs
Signature	
Date	12-14-04

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Docket No. LFS-5015 USNP

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Joel Racchini, et al.  
Serial No. : 10/653,023 Art Unit: 3736  
Filed : 08/28/2003 Examiner: Not Yet Assigned  
For : DEVICES, SYSTEMS AND METHODS FOR EXTRACTING BODILY  
FLUID AND MONITORING AN ANALYTE THEREIN

I hereby certify that this correspondence or fee is being deposited with the  
United States Postal Service as Express Mail (Label No. EL 373 761 292 US) Post Office to Addressee,  
in an envelope addressed to:  
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

12-14-2004  
(Date of Deposit)

Jane Silarajs  
(Name of applicant, assignee, or Registered Representative)

*Jane Silarajs*  
(Signature)

12-14-2004  
(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be

prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for

consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☒ There are no listed references which are not in the English language.

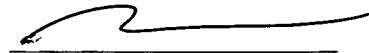
☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/LFS-5015USNP/MM.

Respectfully submitted,



Mayumi Maeda  
Reg. No. 40,075  
Attorney for Applicants

Johnson & Johnson  
International Patent Law Division  
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Dated: 12/1/04



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 5

Application Number	10/653,023
Filing Date	08/28/2003
First Named Inventor	Racchini
Group Art Unit	3736
Examiner Name	unknown
Attorney Docket Number	LFS5015USNP

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		2003/0018300	A1	Duchon et al.	1/23/03	
		2002/0019022	A1	Dunn et al.	2/14/02	
		5,956,501		Brown	9/21/99	
		6,275,717	B1	Gross et al.	8/14/01	
		6,424,847	B1	Mastrototaro et al.	7/23/02	
		6,579,690	B1	Bonnecaze et al.	6/17/03	
		6,233,471	B1	Bemer et al.	5/15/01	
		6,275,717	B1	Kumik	8/7/01	
		6,234,990		Kost et al.	5/22/01	
		6,240,306		Gardner et al.	5/29/01	
		6,251,083		Roe et al.	6/26/01	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
		WO	97/07734	A1	Spectrx, Inc., and Altea Technologies, Inc.	3/6/97		
		WO	01/47408	A1	Roche Diagnostics GmbH	7/5/01		
		EP	1260815	A2	LifeScan, Inc.	11/27/02		
		GB	2375053	A	Agilent Technologies, Inc.	11/6/02		

Examiner Signature	Date Considered
-----------------------	--------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. <sup>6</sup> If possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 5

<b>Application Number</b>	10/653,023
<b>Filing Date</b>	08/28/2003
<b>First Named Inventor</b>	Racchini
<b>Group Art Unit</b>	3736
<b>Examiner Name</b>	unknown
<b>Attorney Docket Number</b>	LFS5015USNP

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		6,272,364		Kumik	8/7/01	
		6,319,210		Grage et al.	11/20/01	
		6,329,161		Heller et al.	12/11/01	
		6,332,871		Radwanski	12/25/01	
		6,514,718		Heller et al.	2/4/03	
		6,558,321		Burd et al.	5/6/03	
		6,702,857		Shults et al.	3/9/04	
		5,002,054		Ash et al.	3/26/91	
		5,139,023		Stanley et al.	8/18/92	
		5,165,418		Tankovich	11/24/92	
		5,174,291		Schoonen et al.	12/29/92	
		5,231,975		Bommannan et al.	8/3/93	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				

Examiner Signature		Date Considered	
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 3 of 5

Application Number	10/653,023
Filing Date	08/28/2003
First Named Inventor	Racchini
Group Art Unit	3736
Examiner Name	unknown
Attorney Docket Number	LFS5015USNP

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,458,140		Eppstein et al.	10/17/95	
		5,706,806		Kissinger	1/13/98	
		6,022,316		Eppstein et al.	2/8/00	
		6,040,194		Chick et al.	3/21/00	
		6,155,992		Henning et al.	12/5/00	
		6,232,130		Wolf	5/15/01	
		6,233,471		Tierney et al.	5/15/01	
		5,582,184		Erickson et al.	12/10/96	
		5,746,217		Erickson et al.	5/5/98	
		5,820,570		Erickson et al.	10/13/98	
		6,080,116		Erickson et al.	6/27/00	
		6,203,504	B1	Latterell et al.	3/20/01	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				

Examiner Signature		Date Considered	
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 4 of 5

<b>Application Number</b>	10/653,023
<b>Filing Date</b>	08/28/2003
<b>First Named Inventor</b>	Racchini
<b>Group Art Unit</b>	3736
<b>Examiner Name</b>	unknown
<b>Attorney Docket Number</b>	LFS5015USNP

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		6,718,189		Rohrscheib et al.	4/6/04	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				

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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 5

<b>Application Number</b>	10/653,023
<b>Filing Date</b>	08/28/2003
<b>First Named Inventor</b>	Racchini
<b>Group Art Unit</b>	3736
<b>Examiner Name</b>	unknown
<b>Attorney Docket Number</b>	LFS5015USNP

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

[illegible]

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1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Joel Racchini et al.  
Serial No. : 10/653,023 Art Unit: 3736  
Filed : 08/28/2003 Examiner: unknown  
For : Devices, Systems and Methods for Extracting Bodily  
Fluid and Monitoring an Analyte Therein

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to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

12-14-2004  
(Date of Deposit)

Jane Silarajs  
(Name of applicant, assignee, or Registered Representative)

  
(Signature)

12-14-2004  
(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450


STATEMENT UNDER 37 C.F.R. §1.97(e)

In accordance with 37 C.F.R. §1.97(e), certification is hereby  
made that:

☒ Each item of information contained in the information  
disclosure statement was first cited in any communication from a  
foreign patent office in a counterpart foreign application not more  
than three months prior to the filing of the Information Disclosure  
Statement; or

☐ No item of information contained in the Information  
Disclosure Statement was cited in a communication from a foreign

patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

---

Mayumi Maeda  
Reg. No. 40,075  
Attorney for Applicants

Johnson & Johnson  
International Patent Law Division  
Attention Philip Johnson  
P.O. Box 1222  
New Brunswick, NJ 08903  
(408) 956-4790  
DATED: 12/18/07

SUBMISSION UNDER MPEP 609 D	Application Number	10/653,023
	Filing Date	08/28/2003
	First Named Inventor	Racchini
	Group Art Unit	3736
	Examiner Name	unknown
	Attorney Docket Number	LFS5015USNP

Page 1 of 1

#### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	U.S. Patent Document		Pages, Columns, Lines, where relevant passages or relevant figures appear
			Number	Kind Code <sup>2</sup> (if known)	
		Sohrab, Borzu	2003/055326	A1	paras.0015-0027, relevant to claims 1,12
		Radwanski, Ryszard et al.	2002/082522	A1	paras. 0022-0025,0033- 0040, 0121-0128, 0137- 0139, relevant to claims 1-5, 9-13
		Roe, Jeffrey N. et al.	2002/022789	A1	paras. 0094-0099, relevant to claims 1,9,10,13
		Freeman et al.	2003/073931	A1	Relevant to claim 1

#### FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	Foreign Patent Document			Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
			Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>		
		LifeScan, Inc.	EP	1260815	A	Relevant to claims 1-3, 10-12, 16	

#### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner 's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		Schmidtke et al., "Measurement and modeling of the transient difference between blood and subcutaneous glucose concentrations in the rat after injection of insulin". Proceedings of the National Academy of Sciences of the United States of America, vol. 95, January 1998 (1998-01), pages 294-299, XP00120307; page 296, column 1-page 298, column 1.	
		European Patent Search Report for Application 04255207.5 dated November 17, 2004	
		Patent Cooperation Treaty International Search Report,European Patent Office, for Application PCT/US2004,018144, dated October 27, 2004.	

Examiner Signature	Date Considered
-----------------------	--------------------